

The new obligations in terms of the EU Product Safety Regulation

TÜV Rheinland Products - Information

July 2023

The EU Product Safety Regulation (GPSR)¹, which has now been published, will regulate the provision of non-food consumer products on the market from December 13th, 2024, after the transition period has expired. The GPSR thus replaces Directive 2001/95/EC and, to a large part, the ProdSG.

In this context, the term "consumer product" is defined more precisely: A product is "any item, whether or not it is interconnected to other items, supplied or made available, whether for consideration or not, including in the context of providing a service, which is intended for consumers or is likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them".

B2B products and stand alone software are therefore not included. Other exceptions are also named, such as food, live plants and animals, antiques.

As before, the requirements in the so-called harmonized area have priority, such as products according to:

- Directive on machinery, (2006/42/EC)
- Low Voltage Directive (2014/35/EC)
- radio equipment and repealing directive (2014/53/EC)
- ...

- For sectors not covered by the harmonized requirements, the requirements of the GPSR apply. For example, for food contact articles according to (EC) No. 1935/2004, the specific safety requirements (migration, sensory, ...) have priority. For the areas not considered, the requirements of the GPSR have to be observed then, e.g., mechanical safety, parallel applicability.

The term "**economic operator**" has been defined more comprehensively. In addition to the manufacturer, there are other actors such as authorized representatives, importers, distributors and fulfillment service providers.

A significant extension of the manufacturer's obligations results from the fact that internal **risk analyses** must now be carried out for all products. This is now part of the required **technical documentation**. Risk-based testing of products should generally be sufficient to address chemical risks.

It also becomes more evident that technical documentation must be kept up to the date, retained for ten years, and that product safety must also be ensured in series production. Such requirements have long been familiar for toys, personal protective equipment, machinery, etc., and are now also required for "trivial products".

When indicating the manufacturer's identification (name, registered trade name or registered trademark, postal address) on the product as a priority, the **e-mail address** must now also be provided.

¹ <https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32023R0988>

The post-market obligations have been significantly extended, especially in the case of knowledge or reason to believe that a **relevant product risk** exists. In addition to immediate corrective action and consumer information, market surveillance must also be informed via the **Safety Business Gateway** ¹ in this case.

This obligation applies immediately in the case of death or damage to health in connection with the use of a product. In our opinion, it is not described in sufficient detail in this context how damage to health is to be regarded; is even the reporting of an allergic reaction a reportable damage to health?

We recommend that you prepare an **emergency plan** for such situations and prepare response mechanisms for possible product risk notifications, in cooperation with experienced lawyers, among others.

A new regulatory framework has been created for online marketplaces and distance selling, linking marketability to the existence of an EU economic operator. We recommend you to analyze these new obligations for distance selling (which areas/departments are responsible for this?) and, if necessary, to adapt the processes of quality assurance, IT infrastructure, design of information obligations (e.g., EU economic operator labeling, manufacturer information, identification labels as well as warning and safety notices).

RECOMMENDATIONS

The new EU Product Safety Regulation (GPSR) does not introduce completely new requirements for the safety of products, but does require measures in individual areas, such as:

- modified labeling (e-mail address)
- risk analysis
- technical documentation
- emergency plan for reporting to the Safety Business Gateway?
- Amendments in the field of online trading

In summary, we recommend that you evaluate the changes in the GPSR in relation to your business processes and prepare and implement measures.

Further information on current legal changes can also be found on our homepage at www.tuv.com or <https://www.tuv.com/regulations-and-standards/en/>.

For further professional information can be obtained from:

TÜV Rheinland LGA Products GmbH
Technisches Kompetenzzentrum Softlines

Dr. Ansgar Wennemer
Wennemer@de.tuv.com

Am Grauen Stein
51105 Cologne
Germany

Info box: You can also find more information about REACH services at: <https://www.tuv.com/germany/de/reach.html>

Disclaimer

This newsletter contains only information of a general nature without specific reference to particular natural or legal persons, objects or circumstances. This newsletter is not to be understood as legal advice and does not replace such advice in any case. TÜV Rheinland LGA Products GmbH (TRLPG) cannot guarantee that all formulations correspond exactly to the respective official versions. TRLPG makes every effort to ensure that the information provided is correct and up to date. Nevertheless, errors and ambiguities cannot be completely ruled out. TRLPG therefore accepts no responsibility for the topicality, correctness, completeness or quality of the information provided.

For the official text, please consult the national or EU Official Journal.

Liability claims regarding damage caused by the use of any information provided, including any kind of information which is incomplete or incorrect, will therefore be rejected.

¹ <https://webgate.ec.europa.eu/gpsd/screen/public/home>